IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

MODERNA'S RESPONSE TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

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TABLE OF ABBREVIATIONS

Abbreviation	Full Description
Moderna	Collectively, Moderna, Inc. and Modernatx, Inc.
Genevant	Genevant Sciences Gmbh
Arbutus	Arbutus Biopharma Corp.
Plaintiffs	Collectively, Arbutus and Genevant
the ’069 patent	U.S. Patent No. 8,058,069
the ’668 patent	U.S. Patent No. 8,822,668
the ’651 patent	U.S. Patent No. 9,504,651
the ’359 patent	U.S. Patent No. 8,492,359
the ’435 patent	U.S. Patent No. 9,364,435
the ’378 patent	U.S. Patent No. 11,141,378
Ratio Patents	Collectively, the ’069, ’359, ’668, ’435 and ’378 patents, of which only the ’359, ’435 and ’378 patents remain asserted.
Asserted Patents	Collectively, the ’651, ’359, ’435 and ’378 patents.
MacLachlan	U.S. Patent App. Pub. No. 2006/0008910
mol % range limitations	Collectively, the cationic, non-cationic, conjugated lipid claim limitations that recite ranges in the Ratio Patents
mRNA	Messenger RNA
siRNA	Small interfering or silencing RNA
pDNA	Plasmid DNA
DOE	doctrine of equivalents
PTO	U.S. Patent and Trademark Office
EDTA	Ethylenediaminetetraacetic acid
WO648	WO 2013/090648
’069 IPR	*Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554 (P.T.A.B.).
’435 IPR	*Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739 (P.T.A.B.).
’069 Appeal	*Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.).

Abbreviation	Full Description
’435 Appeal	*Moderna TX, Inc. v. Protiva Biotherapeutics, Inc.*, No. 2020-1184, -1186 (Fed. Cir.).
LNP	lipid nanoparticle
POSA	Person of ordinary skill in the art
IPR	*inter partes* review
PTAB	Patent Trial and Appeal Board
Op.	Plaintiffs’ Opening Brief in Support of Motion for Summary Judgment, D.I. 519.
FWD	Final Written Decision

I. INTRODUCTION

The Asserted Patents purport to claim priority back to earlier applications filed in 2002 and 2008 that were focused on two specific types of nucleic acids: plasmid DNA ("pDNA") in the '651 Patent and silencing RNA ("siRNA") in the Ratio Patents. When Plaintiffs' efforts to commercialize pDNA and siRNA products failed, they turned their attention to Moderna's innovations in the field of mRNA. As part of their plan to "dominate" the field of mRNA, Plaintiffs spent years filing broader and broader patent applications which eventually resulted in the Asserted Patents. Ex. 30 at 525. The Asserted Patents seek to monopolize "[v]irtually all known LNP formulations" containing mRNA, despite the lack of any enabling disclosure or inventive contribution. Ex. 55 at 981. Plaintiffs now seek to short-circuit the fact-intensive inquiries of obviousness, non-enablement, and derivation through summary judgment, but the factual record demonstrates that genuine disputes remain.

Moderna Is Not Estopped from Raising Obviousness Issues that Have Never Been Fully Litigated: Plaintiffs seek to block Moderna from challenging the obviousness of the '435, '359, and '378 Ratio Patents. Their motion hinges on the flawed premise that these ***broader*** patents present the "identical issue" of obviousness as the ***now-dropped*** '069 patent—the Ratio Patent with the ***narrowest*** claims. SOF¶¶ 44, 132. But the law is clear: issue preclusion does not apply where the issues are not "identical," and Plaintiffs failed to show that the broader claims stand or fall with the narrowest ones. Plaintiffs also urge this Court to impose IPR estoppel on Moderna based on a PTAB decision for the '435 Patent that was never subject to Article III judicial review. That is not the law. Estoppel under 35 U.S.C. § 315(e)(2) does not—and cannot—bar a party from raising invalidity defenses in district court when no federal court has ever reviewed the agency's decision. Plaintiffs' request for an unprecedented expansion of estoppel would deny Moderna its day in court and insulate its patents from judicial review. This Court should reject Plaintiffs'

overreaching attempt to short-circuit the adversarial process and prevent Moderna from presenting its full obviousness defenses to the jury. Summary judgment of non-obviousness should be denied.

Lack of Enablement: The '651 patent broadly claims lipid formulations with certain percentages of "fully encapsulated" mRNA, and the Ratio Patents broadly claim lipid particles with various ratios of lipids together with "nucleic acids," including "mRNA." Yet the Asserted Patents are devoid of ***any*** mRNA teachings or examples; the sole reference to "mRNA" as part of the claimed particles is just one possibility in extensive laundry lists of more than 15 nucleic acids. SOF¶¶ 167–72. The total disconnect between the narrow disclosures of the Asserted Patents on pDNA and siRNA, and their ***claims*** to "mRNA" or the entire genus of "nucleic acids" is fatal to their validity. None of the asserted claims are enabled because the patents do not inform a POSA how to make and use the full scope of the asserted claims as required by 35 U.S.C. § 112. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023) ("[T]he specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.").

Plaintiffs rely on isolated, out-of-context expert statements to suggest Moderna relies on unclaimed limitations and conclusory expert opinions. But Plaintiffs ignore the extensive fact and expert evidence—including Plaintiffs' struggles to develop mRNA formulations years after the earliest priority filings—establishing that undue experimentation ***was*** required to practice the full scope of the claims. At minimum, the competing expert opinions confirm summary judgment is not appropriate. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("[W]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by ***weighing many factual considerations***.").

Plaintiffs Derived the '651 Patent Claims from Moderna: Plaintiffs' early formulation work focused narrowly on lipid formulations to encapsulate pDNA—as reflected in the 2002

patent application to which the '651 patent purports to claim priority. SOF¶¶ 171–72, 210. Plaintiffs did not "***start***" mRNA "delivery research" until 2012, a decade after the asserted priority date of the '651 patent. SOF¶ 204. Indeed, it was not until after Plaintiffs, including named inventor Ian MacLachlan, began monitoring Moderna and its patent filings that Plaintiffs filed the asserted claims of the '651 patent in 2014, seeking for the first time to cover lipid formulations with certain percentages of "fully encapsulated" mRNA. SOF¶¶ 207–08, 216–19. Based on these facts, and those discussed below, there is clear evidence for a reasonable jury to find that Plaintiffs' scheme to claim Moderna's work as its own renders the '651 patent invalid for derivation. *See* 35 U.S.C. § 102(f) ("A person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented."). Plaintiffs' primary argument is that Plaintiffs could not have derived the invention from Moderna because Plaintiffs' earlier 2002 application disclosed it, but Plaintiffs fail to acknowledge that whether that application actually supports the claims of the '651 patent is hotly disputed, foreclosing summary judgment.

II. STATEMENT OF FACTS

Moderna incorporates by reference its Responsive Statement of Facts ("SOF").[1]

III. LEGAL STANDARDS

Summary judgment cannot be granted unless "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In determining the existence of a disputed issue of material fact on a motion for summary judgment, all inferences, doubts, and issues of credibility should be resolved against the moving party." *Meyer v. Riegel Prods. Corp.*, 720 F.2d 303, 307 n.2 (3d Cir. 1983). "[A]t the summary judgment stage the judge's

[1] Exs. 1 to 29 are in the Lachman Decl. (D.I. 526); Exs. 30 to 90 in McLennan Decl.

function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Summary judgment is not appropriate "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248.

IV. ARGUMENT

A. Summary Judgment of Non-Obviousness for the Ratio Patents Should Be Denied Because Issue Preclusion and IPR Estoppel Do Not Apply

The Ratio Patents generally claim nucleic acid lipid particles with varying ratios of four lipid components. The earliest patent in the family, the '069 patent, claimed the narrowest ratios. Over the next decade, Plaintiffs obtained the three broader Ratio Patents that are now asserted. Plaintiffs raise two arguments on summary judgment to shield their broadest Ratio Patents from obviousness challenges. *First*, Plaintiffs claim that Moderna should be estopped from arguing the '435, '359, and '378 Ratio Patents are obvious based on the FWD for a *different* patent (the '069 patent). But the '435, '359, and '378 claims are materially different than the narrow '069 claims, and to find otherwise would require resolving disputed issues of material fact against Moderna on summary judgment. *Second*, Plaintiffs seek to preclude Moderna from arguing that the '435 patent is obvious because Moderna's IPR on that patent was (in part) unsuccessful. Plaintiffs, however, ignore that Moderna was unable to appeal that FWD because Plaintiffs successfully moved to dismiss Moderna's appeal in the Federal Circuit, which held it lacked standing based on Plaintiffs' representations and arguments. Because Moderna was denied judicial review, it is not estopped from raising obviousness as to the '435 patent in this case. Plaintiffs' motion should be denied.

1. Issue Preclusion Based on the Dropped '069 Patent Does Not Apply to Moderna's Obviousness Arguments for the Broader Ratio Patents

Plaintiffs seek to preclude Moderna from arguing obviousness of any claim in the Ratio Patents based on an IPR against the narrowest '069 patent that Plaintiffs no longer assert. However,

issue preclusion only applies when "the ***identical*** issue was previously adjudicated." *Jean Alexander Cosms., Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006). For patents, issue preclusion does not extend to different patent claims unless the "'issues of patentability' are identical, i.e., "where 'the differences . . . do not materially alter the question of invalidity.'" *Finjan LLC v. SonicWall, Inc.*, 84 F.4th 963, 969 (Fed. Cir. 2023). The indisputably broader Ratio Patent claims are materially different to the '069 claims, thus issue preclusion does not apply.

a. Plaintiffs Cannot Show "Identical" Issues Due to Significant Differences in Claim Scope

There is no issue preclusion as to the '435, '359, and '378 Ratio Patents from the '069 IPR because the issues to be litigated are not "identical" to those in the IPR. In determining if "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity," courts consider whether the claims are "substantially similar." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). Here, Plaintiffs admit, and the Court recognized that the asserted claims of the '378 patent "do not relate to the same subject matter" and differ "in a relevant and critical way" from the other Ratio Patents, including the '069. *See* D.I. 266 at 30; D.I. 170 (Plaintiffs' *Markman* Reply) at 58; SOF¶ 140. Similarly, as explained below, the '435 and '359 asserted claims are not substantially similar to those of the '069 patent, such that there can be no issue preclusion. *See TQ Delta, LLC v. 2Wire, Inc.*, 2021 WL 2671296, at *6 (D. Del. June 29, 2021) (denying summary judgment of issue preclusion as to § 103 defenses after unsuccessful IPR to separate claims, where differences in claim scope "materially alter[ed] the invalidity analysis").

The claims of the '435, '359, and '378 patents recite differing ***amounts*** and ***types*** of lipids than the '069, as seen from exemplary claims below:

Table 1: Exemplary Claim Comparison (all amounts are mol%)						
	'069 cl. 1	**'435 cl. 7**	**'435 cl. 16**	**'359 cl. 7**	**'359 cl. 12**	**'378 cl. 2**
Cationic Lipid	50-65	50-85	50-85	50–60	50-65	any amount
Non-cationic lipid	not recited	13-49.5	13-49.5	not recited	not recited	30-55
Phospholipid (non-cationic lipid)	4-10	3-15	not recited	3–15	6-12	3-15
Cholesterol (non-cationic lipid)	30-40	any amount	not recited	30–40	30-40	25-45
Conjugated Lipid	0.5-2	0.5-2	0.5-2	0.5-2	0.5-2	0.1-2

SOF¶¶ 44, 132–134; Ex. 31 (Anderson) ¶ 79 (providing similar comparison chart).

As shown above in Table 1, the Ratio Patents claim far broader lipid ranges than the '069 patent. For example, '435 claim 7, '359 claim 7, and all asserted claims of the '378 patent recite a phospholipid range ***twice*** as broad as claim 1 of the '069 patent. SOF¶¶ 132–133. *Cf. Wirtgen Am., Inc. v. Caterpillar, Inc.*, 746 F. Supp. 3d 218, 231 (D. Del. 2024) (Wolson, J.) (concluding in issue preclusion context that invalidation of broader claim "does not doom the narrower one"). As Plaintiffs concede,'435 claims 8 and 16 do not recite ***any*** amount of phospholipid. Op. 15; SOF¶ 44, 132. In fact, although the '069 claims recite four lipids, '435 claim 16 only requires three. And none of the '378 claims limit the amount of cationic lipid. SOF ¶¶ 44, 132. As explained below, Plaintiffs' arguments during prosecution and in this lawsuit emphasizing these differences in claim scope directly contradict any assertion that issues are "identical."

During *Markman*, Plaintiffs argued that the other Ratio Patent claims "differed in a relevant and critical way from the asserted '378 patent claims: they included explicit limitations requiring particular amounts of cationic lipid," whereas the "asserted claims of the '378 patent do not." D.I. 170 at 58 (comparing '069 claim 1 to '378 claims); SOF¶¶ 140–141. For that reason, the Court concluded that the claims of the '378 patent "do not relate to the same subject matter" as the remaining claims of the Ratio Patents. D.I. 226 at 30. Dr. Anderson recognized this difference:

"Dr. Murthy's criticality argument . . . is undermined . . . by the claims of the '378 Patent, which express no lower limit (or upper limit) to the cationic lipid." Ex. 36 (Anderson Reply) ¶ 186. Plaintiffs also successfully obtained reconsideration on the number of patents that they could maintain prior to summary judgment *because of* these differences. Specifically, Plaintiffs argued that the Ratio Patents ***"differ in really important ways***." SOF¶ 142. And that it would be unjust if they could only maintain two Ratio Patents. D.I. 469. Plaintiffs' arguments succeeded: the Court reconsidered its narrowing order and allowed Plaintiffs to assert an additional patent based on Plaintiffs' arguments that the Ratio Patents differed. D.I. 475 ¶¶ 7, 9; SOF¶ 142.

Completely ignoring their prior statements, Plaintiffs argue that prior art cited by Moderna's expert Dr. Anderson does not present "materially different" issues from what was previously decided. Op. 13–15. But Plaintiffs ignore that he and other experts opined on the significant differences in claim scope between the '069 patent claims and the asserted claims that "materially alter the question of invalidity," *Ohio Willow Wood*, 735 F.3d at 1342, including:

- Plaintiffs' alleged invention dates differ between the '069 claims and certain asserted claims (SOF¶ 145). According to Dr. Murthy's analysis, Jadhav, one of Moderna's obviousness references, would only be prior art against the claims with the later invention date, and not the claims with the earlier invention date (*id.*).

- Plaintiffs alleged secondary considerations in the '069 IPR based on Alnylam's siRNA product Onpattro, which Plaintiffs concede is not covered by ***all*** asserted Ratio claims. SOF¶¶ 146–48.

- The only working example formulation the Ratio Patents is the 1:57 formulation, which Plaintiffs relied heavily on for unexpected results in the '069 IPR, but Plaintiffs concede here that it is ***not*** covered by all asserted claims of the Ratio Patents (SOF¶¶ 149–51).

- Dr. Prud'homme opined that evidence of Alnylam's simultaneous inventions—obtained through third-party discovery—weigh in favor of obviousness. *Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010) ("Independently made, simultaneous inventions, made within a comparatively short space of time, are persuasive evidence that the claimed apparatus was the product only of ordinary mechanical or engineering skill."). He cites formulations Alnylam independently developed by optimizing lipid ratios around the time of the alleged invention, including one that falls within certain asserted Ratio Patent claims, but not the '069 Patent claims (SOF¶ 152).

Plaintiffs do not acknowledge these differences. But because the differences materially alter the invalidity analysis, summary judgment should be denied. *TQ Delta*, 2021 WL 2671296, at *6; *Papst Licensing GmbH & Co., KG v. Samsung Elecs. Co.*, 403 F. Supp. 3d 571, 602 (E.D. Tex. 2019) (concluding moving party failed to show collateral estoppel applied to unadjudicated patents claims where different prior art combinations were used).

b. Routine Optimization Analysis Is Grounded in the Asserted Claims and Prior Art, which Differ from the '069 IPR

Despite failing to establish that the claims of the remaining Ratio Patents are substantially similar to the '069 patent claims, Plaintiffs seek to prevent Moderna from raising "routine optimization" for all Ratio Patents. But "routine optimization" analysis "is rooted in the decades-old legal principle that where the general conditions of a ***claim*** are disclosed in the prior art . . ." *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1347 (Fed. Cir. 2024). Under such analysis, "an overlap between a ***claimed range*** and a prior art range creates a presumption of obviousness that can be rebutted with evidence that the given parameter was not recognized as result-effective." *Id.* (emphasis omitted). A presumption of obviousness "established by the overlap of prior art values with the claimed range can be rebutted by evidence that the ***claimed range*** is critical because it achieves unexpected results." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012). "Routine optimization" is thus inextricably linked to the scope of the ***claims***. *Pfizer*, 94 F.4th at 1348 ("A routine optimization analysis generally requires consideration whether a [POSA] would . . . bridge any gaps in the prior art to arrive at a ***claimed*** invention.").

Such an analysis is intensely factual on a claim-by-claim basis. *Fitness Anywhere LLC v. Woss Enters. LLC*, 2017 WL 1833471, at *3 (N.D. Cal. May 8, 2017) (explaining "section 103 requires a fact-intensive comparison of the claimed process with the prior art"). Thus, obviousness analysis is necessarily different for the '069 patent and the remaining Ratio Patents. For example,

Plaintiffs argued in the '069 IPR that the prior art "ranges are much ***broader*** than ***the claimed range of 50 mol% to 65 mol%*** recited in the challenged ['069] claims." SOF¶ 153. But as shown above in Table 1, the cationic range in the '435 patent claim 16 is more than ***twice*** as broad as the '069 patent claim 1, and the '378 patent claims are not limited to ***any*** range. SOF¶¶ 132–33. Plaintiffs argued the '069 IPR "turned on" the "'unpredictable interactivity between the' ***four*** recited lipid components," whereas the '435 patent claim 16 recites three lipids. Op. 15. Routine optimization for the '069 patent claims and the broader asserted claims is not one "identical" issue.

"When an applicant seeks to overcome a prima facie case of obviousness by showing improved performance in a range that is within or overlaps with a range disclosed in the prior art, the applicant must show that the ***[claimed] range*** is *critical*, generally by showing that the ***claimed range*** achieves unexpected results relative to the prior art range." *In re Patel*, 566 F. App'x 1005, 1011 (Fed. Cir. 2014). Whether Plaintiffs can rebut a presumption of obviousness by evidence that the ***claimed range*** is critical will involve different issues to those decided in the '069 IPR. In this lawsuit, Plaintiffs' arguments also belie any "criticality" of claimed ranges such that the presumption of obviousness ***cannot*** be rebutted. Plaintiffs assert many claims with disparate ranges of the four lipids, and it is impossible that ***all*** such ranges are "critical." *See* Table 1; SOF¶¶ 44, 132 (asserted claims reciting 3-15, or 6-12 mol% phospholipid, 35-45, 25-45, 30-40 mol% cholesterol). Additionally, Plaintiffs' DOE infringement theory provides that the claimed ranges for three lipids are equivalent to amounts ***outside*** the claimed ranges—defeating any suggestion of criticality. *E.g.*, SOF ¶¶ 159–64; Ex. 36 (Anderson Reply) ¶ 188.

The FWD in the '069 IPR, including its finding on "routine optimization," was expressly based on the evidence and arguments before it. SOF¶ 16. Given the substantially different evidence, arguments, and claims at issue here, it cannot be said that "the ***identical*** issue" of routine

optimization was previously adjudicated. *Jean Alexander Cosmetics*, 458 F.3d at 249. Here, Plaintiffs' expert Dr. Murthy cited references from the alleged priority date demonstrating that large-scale lipid formulation screening ***was*** routine. Ex. 36 (Anderson Reply) ¶¶ 149, 151 (responding to Dr. Murthy references raised); SOF¶ 154. Dr. Murthy, in rebutting non-enablement (which was not at issue in the IPR), also conceded that "the actual making and using of those lipid particles was, by the mid-2000s, a ***routine*** process that scientists with the qualifications of the POSA could have carried out with little trouble or experimentation." Ex. 35 (Murthy) ¶ 1299; SOF¶ 154. This is consistent with Plaintiffs' internal documents, which noted that they merely "tinkered" with a prior art formulation to obtain the formulation disclosed in the Ratio Patents. SOF¶ 155; Ex. 36 (Anderson Reply) ¶ 151. Dr. Anderson also analyzed many teachings in prior art not at issue in the IPR—demonstrating motivations to alter the amount of the claimed lipids. *See, e.g.*, Ex. 31 (Anderson) ¶ 720–722 (explaining prior art showing "cationic lipid was varied at the expense of phospholipid" and "increasing the cholesterol and while maintaining the total neutral lipid"), ¶ 992 (quoting prior art that disclosed "[h]aving been taught the various lipid-plasmid particle formulations . . . it would be obvious to one skilled in the art to modify them. . ."); SOF¶ 156. These differences in evidence and arguments—on top of the significant differences in claim scope—preclude any finding that the issue of "routine optimization" is "identical" to what was decided in the '069 IPR.

c. The "Phospholipid Range" Finding Has Been Relitigated by Plaintiffs, and Does Not Apply to All Prior Art and Claims

Plaintiffs seek to preclude Moderna from arguing that two prior-art references teach a phospholipid range found in the '069 claims—4-10 mol %. Op. 16. But Plaintiffs dropped the narrowest '069 patent, and ***no*** asserted claim recites that same phospholipid range. SOF¶¶132–34.

First, Plaintiffs impermissibly group claims together, without analyzing them individually,

and ignore the "interdependence" of the (varying) phospholipid ranges with the other claimed lipids. *See ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1376 (Fed. Cir. 2021) (crediting "interdependence of the claimed lipid components and how adjustments would affect the nucleic acid-lipid particle as a whole"). Moderna expects that Plaintiffs would strenuously object to Moderna asking the Court to making a finding that the cationic lipid and PEG lipid ranges of the '435 Patent that PTAB found in the prior art apply equally to all Ratio Patent claims. SOF¶4, n1. But that is what Plaintiffs seek here, effectively asking this Court to find that ***any*** "phospholipid range"—in isolation—is not obvious in ***any*** claim, regardless of the amount of phospholipid or the other limitations. When properly applying the law of issue preclusion, the "phospholipid range" finding is materially different for the asserted claims and prior art at issue in this lawsuit. For example, '435 claims 8 and 16 do not recite ***any*** amount of phospholipid, and thus materially differ from the '069 claims. Ex. 36 (Anderson Reply) ¶¶ 163, 165; SOF¶ 157. Not to mention Dr. Anderson opined about prior-art phospholipids that were ***not*** at issue in the '069 IPR and about claims with different lipid ratios. Op. 13–15; SOF¶¶ 40–41, 132–34, 157–158.

Plaintiffs also seek to preclude Moderna from arguing a POSA could determine the percent of phospholipid in a particle "by adding up the amounts of the other three components and subtracting from 100%." Op. 16 (citing *ModernaTx*, 18 F.4th at 1374–75). But ***Plaintiffs themselves relied on the exact same "premise"*** in this litigation to win their proposed construction of the '378 patent claims. Specifically, in arguing that the '378 patent disclosed particles with less than 50 mol % cationic lipid, Plaintiffs pointed to disclosures of ***other*** lipids at over 50 mol % (i.e., subtracting those other lipids from 100 mol % to find the mol % of cationic lipid). SOF¶ 139. Given that Plaintiffs themselves recognized that there was no preclusion on this point, and successfully used it to obtain their desired construction, Moderna should not now be precluded

from relying on the same "premise" in support of obviousness.

2. IPR Estoppel Does Not Apply to Moderna's Obviousness Arguments for the '435 Patent Which it Could Not Appeal

In the years before the IPRs, Plaintiffs publicly (and incorrectly) stated Moderna's pipeline products were covered by its "dominating" patent estate, including the Ratio Patents. SOF¶¶ 143–44. Given this environment, Moderna filed IPRs challenging the '069 and '435 patents. SOF¶¶ 3, 11, 144. For the '435 patent, Moderna successfully invalidated ten claims, while other claims were upheld. SOF¶¶ 4, 137–38. Moderna sought to appeal the finding as to the patentable claims, but Moderna's appeal was dismissed for lack of standing after Arbutus argued Moderna lacked standing where "there [was] no existing or imminent threat of infringement." SOF¶¶ 6, 135. As soon as time lapsed for Moderna to seek review of the'435 appeal, Plaintiffs filed this suit. SOF¶ 136. Now, Plaintiffs aim to foreclose Moderna from arguing obviousness of the '435 patent based on IPR estoppel under § 315(e). Plaintiffs' argument should be rejected.

This Court should not assume that § 315(e) upended longstanding principles of issue preclusion that a ruling does not have preclusive effect unless a party has opportunity to appeal. *Penda Corp. v. United States*, 44 F.3d 967, 973 (Fed. Cir. 1994) ("It is axiomatic that a judgment is without preclusive effect against a party which lacks a right to appeal that judgment."). Indeed, "Congress legislate[s] against a background of common-law adjudicatory principles, and it expect[s] those principles to apply except when a statutory purpose to the contrary is evident." *Minerva Surgical, Inc. v. Hologic, Inc.*, 594 U.S. 559, 572 (2021) (cleaned up). Section 315(e) provides ***no*** indication that principles of issue preclusion were intentionally excluded. Moreover, the Federal Circuit "has not decided" "whether § 315(e) would have estoppel effect even where the IPR petitioner lacked Article III standing to appeal the Board's decision to this court." *AVX Corp. v. Presidio Components, Inc.* 923 F.3d 1357, 1363 (Fed. Cir. 2019); *see also Gen. Elec. Co.*

v. United Techs. Corp., 928 F.3d 1349, 1359 (Fed. Cir. 2019) (Hughes, J., concurring). Plaintiffs cite no district court decision that has either.

Plaintiffs argue that in *Click-to-Call Techs. LP v. Ingenio, Inc.*, 45 F.4th 1363 (Fed. Cir. 2022), the Federal Circuit "expressly rejected an attempt to import the 'issue-preclusion rubric' into statutory 'IPR estoppel.'" Op. 9. But that case did not address estoppel in the circumstances here, where the patent challenger lacked standing to appeal. In deciding that the defendant could not raise certain arguments, the Federal Circuit focused on the "actually litigated" requirement of issue preclusion, concluding that § 315(e) included plain language excluding the requirement that the issue be "actually litigated." *Click-to-Call*, 45 F.4th at 1368 ("[I]t would not be reasonable to engraft such a requirement into IPR estoppel, given that the IPR statute also estops grounds that reasonably ***could have*** been raised.") (cleaned up). But nothing in §315(e) suggests that it upends the well-established principle that preclusion does not apply if a party did not have an opportunity to appeal the decision. Plaintiffs' remaining cases relate to non-analogous scenarios where the accused infringer did or would have had standing to appeal to an Article III court. Op. 5–10.[2] Plaintiffs also cite decisions on standing to appeal IPR decisions, but none applied IPR estoppel where a petitioner could not appeal the PTAB decision. Op. 8.[3]

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[2] *See Trustees of Columbia Univ. v. Symantec Corp.*, 390 F. Supp. 3d 665, 668–669, 671, 672–673 (E.D. Va. 2019) (petitioner with standing to appeal IPR); *Trustid, Inc. v. Next Caller Inc.*, 2021 WL 3015280, at *1 (D. Del. July 6, 2021) (same); *TRUSTID, Inc. v. Next Caller, Inc.*, 2021 WL 4427918, at *1 (Fed. Cir. Sept. 27, 2021) (appeal of IPR); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 593, 598–601 (D. Mass. 2018) (petitioner with standing to appeal IPR); *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1283 (Fed. Cir. 2023) (IPR filed after district court suit); *Intuitive Surgical, Inc. v. Ethicon LLC*, 25 F.4th 1035, 1041 (Fed. Cir. 2022) (petitioner appealed first two IPRs).

[3] *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1175-76 (Fed. Cir. 2017); *Consumer Watchdog v. Wis. Alumni Rsch. Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014); *JTEKT Corp. v. GKN Automotive Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018); *Argentum Pharms. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374, 1378 (Fed. Cir. 2020); *Gen. Elec. Co.*, 928 F.3d at 1355; *Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378, 1385 (Fed. Cir. 2021).

Plaintiffs' argument that "[i]t cannot be the case that estoppel applies to prevent obviousness assertions before or during an appeal but no longer applies when an appeal is *unsuccessful* upon dismissal" misses the point. Op. 7. A party appealing the agency decision on its merits to the Federal Circuit ***would*** have judicial review. By contrast, here, Moderna has had ***no*** such opportunity for the '435 asserted claims. That result is particularly unjust given the Federal Circuit found Moderna lacked standing to appeal the '435 IPR after Plaintiffs argued there was no imminent threat of suit. SOF¶ 135. The Federal Circuit recognized as much, noting in its decision for the '069 Appeal that such a result would "perversely incentivize a future similarly situated patent owner to remain silent regarding its intentions during the pendency of an appeal and wait to sue for infringement until after the appeal has been dismissed for lack of standing." *ModernaTx*, 18 F.4th at 1372. Plaintiffs did just that for the '435 Patent.

Finally, denying summary judgment also provides practical efficiencies. If Plaintiffs' motion were granted and this issue were taken from the jury and Moderna prevailed on appeal, the result would require a second trial on obviousness of the '435 patent. *See Trustid*, 2021 WL 3015280, at *4 (declining to stay trial on specific claims until after appeal because "to do so risks more significant inefficiencies for the Court and the parties, including a possible second trial"). No similar risk exists if Moderna is permitted to present obviousness even if the Federal Circuit later decides § 315(e) precluded that defense.

B. There Are Genuine Disputes of Material Fact that the Asserted Claims Are Not Enabled, Precluding Summary Judgment

"[E]nablement requires that the specification teach [POSAs] to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d at 737. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* The eight "*Wands* factors" include, for example, the

quantity of experimentation required to practice the claims, the absence of working examples, the unpredictability in the art, and claim breadth—all factual considerations. *Id.* Moderna has three non-enablement theories for the Ratio Patents (which Plaintiffs call "Lipid Composition Patents"), and three for the '651 patent. For each theory, Moderna set out detailed expert testimony and documentary evidence supporting its position. Plaintiffs and its expert disagree, and it is for the jury, not the Court on summary judgment, to decide whose arguments to credit.

1. Ratio Patents

a. Moderna's enablement arguments are based on the claims

Moderna is pursuing three lack of enablement theories related to the following Ratio Patent claim limitations: (1) "a nucleic acid" / "an RNA" / "mRNA" ('435, '378 patent); (2) "__ mol % the total lipid present in the particle" ('435, '359 patent); and (3) "administering to a mammalian subject a nucleic acid lipid particle" ('435 patent). SOF¶ 182. The overbroad nature of the claims bears a striking resemblance to the claims in *Consolidated Electric Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895). In *Consolidated*, plaintiffs obtained a broad patent for an "electric lamp" with a conductor made of "carbonized fibrous or textile material," even though the lamp they invented only used carbonized paper. 159 U.S. at 471. When Thomas Edison later invented his lamp using "fibrous" bamboo, the plaintiffs sued for infringement seeking to share in some of Edison's success. But the Court found those claims invalid for lack of enablement because they were not limited to what was actually invented and instead tried to claim "all fibrous materials" without teaching how to use them. *See Consolidated*, 159 U.S. at 472, 476 ("[T]he fact that paper happens to belong to the fibrous kingdom did not invest [plaintiffs] with sovereignty over this entire kingdom."). Plaintiffs here likewise seek to claim an "entire kingdom" of nucleic acid lipid particles, instead of confining themselves to lipid particles consisting of siRNA.

For the terms "a nucleic acid" / "an RNA" / "mRNA," Moderna's experts Drs.

Prud'homme and Meulien explained that all examples are directed to formulating one "nucleic acid: siRNA," with mRNA mentioned only once as a potential delivery agent in a laundry list of "nucleic acids." *E.g.*, Ex. 32 (Prud'homme) ¶ 288; Ex. 45 (Meulien) ¶¶ 45–47, 66; SOF¶¶ 167–70. Dr. Prud'homme then explained the impact of the "broad range of structures and other properties of the various nucleic acids that appear in this laundry list." Ex. 32 (Prud'homme) ¶ 241. Indeed, Plaintiffs' internal documents reported that "a lot of the rules that apply to formulating small siRNA duplexes are completely reversed when considering large mRNA transcripts." Ex. 44 (Prud'homme Reply) ¶ 175 (citing Ex. 51 GENV-00304863 at 864-865); *see also* Ex. 44 (Prud'homme Reply) ¶ 175 (citing Ex. 57, GENV-00490277 (Arbutus former CEO Mark Murray stating, "Successfully formulating mRNA is not trivial; it is large and bulky"). Ex. 32 (Prud'homme) ¶ 253; SOF¶¶ 176–78. Plaintiffs responded to Dr. Prud'homme's report with its own lengthy expert report, disputing Moderna's factual allegations, demonstrating that this question may not be decided at summary judgment. Ex. 35 (Murthy) ¶¶ 1230–52, 1279–87, 1338–45. To avoid these factual inquiries, Plaintiffs attack a handful Dr. Prud'homme's opinions related to a subset of the eight *Wands* factors, arguing (incorrectly) that his opinion is premised on unclaimed functional limitations. Op. 19–21. But Plaintiffs fail to address his opinions for the rest of the *Wands* factors, and the underlying documents that ***alone*** establish undue experimentation. *Bausch & Lomb Inc. v. SBH Holdings LLC*, 2025 WL 929635, at *4 (D. Del. Mar. 27, 2025) (finding as to enablement, other evidence of record, without expert testimony, sufficient to "establish a genuine issue of material fact precluding summary judgment in Plaintiffs' favor").

Regarding the term "__ mol % the total lipid present in the particle," Dr. Prud'homme opined that the claims are directed to a "very broad range of possible compositions," and that a POSA "would [] perceive a wide range of possible permutations of the components (both in terms

of the specific lipid to be used from each category as well as the molar ratio of said lipid) and therefore a wide breadth of possible compositions." Ex. 32 (Prud'homme) ¶ 240. For example, "[e]ven putting aside the range of possible molar ratios," the claims covered "more than 2,500 possible combinations of possible lipids" based on just some examples of the claimed lipids identified in the Ratio Patents. Ex. 32 (Prud'homme) ¶ 242. For the claims reciting a "nucleic acid," which includes at least 15 types in the laundry list, "that number climbs to more than 20,000 possible combinations." *Id.* The claims are then further enlarged exponentially, because they encompass each of those 20,000 combinations with every possible combination of lipid mol% within the claimed ranges for each lipid. The extreme breadth of these claims, coupled with at least the limited examples to siRNA (***not*** mRNA or any other nucleic acid), at a minimum, raises a genuine issue of material fact as the full scope of the claims were enabled as of 2008. SOF ¶182; *Amgen*, 598 U.S. at 613 ("[T]he more a party claims, the broader the monopoly it demands, the more it must enable."); *see also Wyeth v. Mylan Pharms., Inc.*, 2009 WL 3335062, at *13 (N.D. W.Va. Oct. 14, 2009) ("Given that genuine questions of fact remain as to at least two of the *Wands* factors, the Court need not consider any remaining factors" to "determine[ ] genuine questions of material fact are in dispute as to the issue of enablement[.]").

As to the term "administering to a mammalian subject a nucleic acid lipid particle," Dr. Prud'homme explained that ***all examples utilize and relate only to siRNA***—there is "no other disclosure of delivering or administering any other nucleic acids," including mRNA. Ex. 32 (Prud'homme) ¶ 328. Moderna presented extensive evidence that the "specification provides ***no*** guidance as to whether any different or additional steps need to be taken to deliver a different payload." *Id.*; *see also* Ex. 45 (Meulien) ¶¶ 50–111. Aside from a generic citation to Dr. Prud'homme's report (Op. 23, citing ¶¶ 327–33), Plaintiffs' brief ***does not identify any evidence***

or argument related to this claim limitation to refute this. Plaintiffs failed to demonstrate no genuine issue of material fact exists as to this theory. *See In re Asbestos Litig.*, 2023 WL 122510, at *5 (D. Del. Jan. 6, 2023), *report and recommendation adopted*, 2023 WL 372161 (D. Del. Jan. 24, 2023) (concluding "[movant] has not carried its burden" with conclusory arguments).

As Plaintiffs are aware, Moderna dropped certain lack of enablement theories as part of the case narrowing; thus, their attacks on theories no longer asserted cannot support summary judgment. Op. 21 (citing Ex. 32 (Prud'homme) ¶¶ 193, 324); SOF¶ 182. For that reason, Plaintiffs' reliance on *In re Merch.,* 575 F.2d 865, 868 (C.C.P.A. 1978) and *Invista N. Am. S.A.R.L. v. M & G USA Corp.,* 35 F. Supp. 3d 583, 599 n.12 (D. Del. 2014) is misplaced.

b. Moderna Correctly Applied the *Wands* Factors to Show Undue Experimentation

Moderna's expert provided 16 pages of opinions showing undue experimentation was required to practice the claims. That analysis is incorporated into each of the three theories above. Ex. 32 (Prud'homme) ¶¶ 238–65. Plaintiffs take issue with only three paragraphs of that analysis by alleging Moderna imports unclaimed functional requirements into the claims. Op. 20–21. Not so. Moderna's expert correctly applied the *Wands* factors to show that making and using the full scope of the ***claims*** required undue experimentation. *In re Wands*, 858 F.2d at 736–40.

The first paragraph Plaintiffs cite, Ex. 32 (Prud'homme) ¶ 251, addresses the nature of the invention (i.e., a *Wands* factor) in the context of certain advantages that the patents themselves identify as the "present invention." This is exactly what *Wands* contemplates and requires. Next, Plaintiffs criticize a paragraph that recites ***Plaintiffs' own IPR statements*** relying on the unpredictability in the art as a basis for explaining why its patents are not obvious. Ex. 32 (Prud'homme) ¶ 252. Again Dr. Prud'homme appropriately assessed Plaintiffs' own admissions about unpredictability in the art—one of the *Wands* factors. *In re Wands*, 858 F.2d at 736–40.

Next, Plaintiffs take issue with Dr. Prud'homme's statement that "to determine whether a given formulation can achieve this higher level of potency, a POSA would be required to undergo undue experimentation. . . ." Ex. 32 (Prud'homme) ¶ 265; Op. 20. Plaintiffs omit that Dr. Prud'homme's full opinion was that the Ratio Patents do not teach a POSA what structural features support the "formulation" of a particle implicit in the claims. *Id.* For this reason, Dr. Prud'homme opined that "despite claiming a broad set (or genus) of compositions . . . the specification fails to identify any common structures or other characteristics that facilitate the formation of these particles, let alone with the in vivo properties described in the specification." *Id.* Instead, the Ratio Patents—which are focused on siRNA—teach alleged advantages of the particles but do not inform a POSA how to ***make*** and ***use*** them, including the implicit structural features of the claims.

Moreover, Moderna's arguments addressing the so-called "unclaimed functional" limitations were only necessary to ***rebut Plaintiffs' position*** that the claims required certain functional properties. For example, Plaintiffs made statements in the IPRs that the claims required certain properties (*e.g.*, arguing "'nucleic acid-lipid particle' should be construed as necessarily including a nucleic acid encapsulated in the lipid portion of the particle, thereby protecting it from enzymatic degradation"). Ex. 33 ('069 IPR, POR, at 9); SOF ¶ 166. Relying on these statements, Moderna's experts provided enablement opinions in the alternative, in case Plaintiffs invoked those properties again to embellish their "inventions" here. *See* Ex. 32 (Prud'homme) ¶ 288 (opining "***to the extent*** [i.e., if] the claims are directed to particles with specific properties (e.g., stability)," there was inadequate disclosure); SOF ¶¶ 54, 59. In rebuttal, Plaintiffs' expert Dr. Murthy confirmed that—contrary to what Plaintiffs argued in the IPR—the claims do not require these properties. Ex. 35 (Murthy) ¶¶ 1236, 1243, 1271, 1275. Thereafter, both Drs. Prud'homme and Anderson agreed that the claims did not require unclaimed properties. Ex. 44 (Prud'homme

Reply) ¶ 286; Ex. 36 (Anderson Reply) ¶¶ 194, 213. Regardless, Moderna's non-enablement theories are not predicated ***solely*** on these properties. SOF ¶¶ 174, 176-81. This was just one of many reasons for why the claims are not properly enabled. *See* SOF¶¶ 174, 176-81.

Additionally, Plaintiffs' cited cases on "unclaimed" limitations are inapposite regardless. Op. 21. Enablement was not at issue in *Golight, Inc. v. Wal-Mart Stores, Inc.,* 355 F.3d 1327 (Fed. Cir. 2004). Nor has Moderna made any arguments about the safety of the claimed invention. *See United Therapeutics Corp. v. Liquidia Techs., Inc.,* 74 F.4th 1360, 1370 (Fed. Cir. 2023). And, in *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.,* the defendant "proffered ***no*** evidence that any experimentation, let alone undue experimentation . . . would be necessary in order to practice the claimed invention." 745 F.3d 1180, 1189 (Fed. Cir. 2014). That is not the case here, where there is extensive evidence—including Plaintiffs'—that the full scope of the claims is not enabled.

c. Evidence Supporting Lack of Enablement Raises Fact Disputes

Plaintiffs next argue that the remainder of Moderna's expert opinions are unsubstantiated. But baked into Plaintiffs' arguments are inaccurate propositions for what Moderna must show to establish undue experimentation. For example, Plaintiffs argue that Moderna does not "adduce any evidence that any scientist ever has been unable to practice the claims." Op. 22. Aside from being factually incorrect, Plaintiffs do not cite to any case law suggesting that real-world evidence of failure is required. Rather, "[c]laims are not enabled when, ***at the effective filing date of the patent***, [a POSA] could not practice their full scope without undue experimentation." *Wyeth and Cordis Corp. v. Abbott Lab'ys.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013).

Plaintiffs claim that Moderna's experts only offer "ipse dixit" to support their opinions. That is not true. Op. 23. Dr. Prud'homme spent 25 pages discussing undue experimentation. SOF ¶¶ 174, 176–81; Ex. 32 (Prud'homme) ¶¶ 238–65, 287–90, 327–31; Ex. 44 (Prud'homme Reply) ¶¶ 162–66; 173–77; 210–13. Dr. Prud'homme opined, for example, about the breadth of the

claims, including the more than 20,000 possible permutations of nucleic acid-lipid particles despite the patent only exemplifying two siRNA formulations (the 1:62 and 1:57). SOF¶¶ 74, 170; Ex. 32 (Prud'homme) ¶¶ 242, 248. He also opined on the unpredictability in the field based on Plaintiffs' statements that varying the proportion of lipids "would be unpredictable." SOF¶ 176. Dr. Meulien opined in over 25 pages on the differences between various types of nucleic acids. Ex. 45 (Meulien) ¶¶ 50-123, 156–59; Ex. 46 (Meulien Reply) ¶¶ 41–44. For example, Dr. Meulien explained how "each type of RNA behaves differently chemically." SOF¶ 176; Ex. 45 (Meulien) ¶¶ 81, 82–93. And Dr. Meulien observed how "Plaintiffs' own research indicated that many 'of the rules that apply to the formulating of small siRNA duplexes are completely reversed when considering large mRNA transcripts.'" SOF¶ 178; *Id.* ¶ 158 (citing GENV-00304863 at 865). He also discussed Plaintiffs' communications about how "mRNA transcript size adversely affected formulation and that they were experiencing difficulty formulating an mRNA transcript of about 2000 nucleotides." SOF¶ 178. Each of these points (and more) are supported by record evidence demonstrating that undue experimentation was required to practice the claims. Plaintiffs' vague assertions that Moderna's expert testimony is "conclusory" is itself unsupported and cannot transform factual questions into a legal question.

Plaintiffs also disagree with Dr. Prud'homme's opinions that "undue experimentation was required to measure the lipid composition of a 'particle.'" Op. 23–24 (i.e., measuring "__ mol %"). Specifically, Dr. Prud'homme opined that because "***Plaintiffs have taken the position*** that the claims are directed to the composition of a single particle," then enablement requires a POSA to ascertain the concentration of lipids within a particle that they were ***varying*** across the claimed ranges. *See* SOF¶ 180; Ex. 32 (Prud'homme) ¶¶ 256, 258; Ex. 35 (Murthy) ¶¶ 1206, 1232 ("POSA would have been readily able to make and use lipid particles having a ***variety*** of different lipid

molar ratios"). *See Tailored Lighting, Inc. v. Osram Sylvania Prods., Inc.*, 713 F. Supp. 2d 184, 193–94 (W.D.N.Y. 2010), *amended on denial of reconsideration*, 789 F. Supp. 2d 411 (W.D.N.Y. 2011) (finding no enablement where "[t]he person attempting to make the bulb can then only engage in trial and error to see if he or she can make a bulb with a coating that emits a light that is substantially similar to a desired daylight," and, . . . only then can the maker work backwards to determine whether or not the coating of the bulb comports to the formula disclosed in Claim 1."). Given there is no methodology today (let alone in 2008) to isolate and measure the composition of a single particle, Dr. Prud'homme opined that "a POSA would be required to undergo undue experimentation to determine whether a certain composition falls within the claims." *See* SOF¶ 180; Ex. 32 (Prud'homme) ¶¶ 256, 258; Ex. 35 (Murthy) ¶ 1206. Dr. Prud'homme thus properly considered the "ambiguities and lack of specified boundary" in the scope of the asserted claims as part of the difficulties in practicing the ***claims***. *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1379 (Fed. Cir. 2002). Plaintiffs also misleadingly suggest Dr. Prud'homme agreed that there ***was*** a standard method to measure each lipid particle's composition. Op. 24. In fact, he explained the opposite: while HPLC can measure lipid content of ***aggregate formulations*** (i.e. ***many*** LNPs), "there is ***no*** widely accepted methodology by which to measure the composition of a single particle," which is what Plaintiffs argue the claims require. SOF¶¶ 70–71.

Plaintiffs' final argument that claims with inoperable embodiments may still be enabled also misses the mark—that is not what Moderna's experts opined. Op. 24. As explained above, these experts argued that the full scope of the claims was not enabled in view of the specification. *See* Ex. 44 (Prud'homme Reply) ¶¶ 162–66, 209; Ex. 45 (Meulien) ¶ 157–58; Ex. 46 (Meulien Reply) ¶ 43. To the extent Plaintiffs dispute this, that again is a fact question for a jury.

2. The '651 Patent

a. Moderna's non-enablement arguments raise fact questions

Moderna's lack of enablement theories for the '651 patent relate to the following claim limitations: (1) "fully encapsulated," (2) "at least [about] 70% [/80%/90%] of the mRNA . . . is fully encapsulated," and (3) "mRNA." SOF¶ 183. Moderna's experts opined, based on extensive evidence (including Plaintiffs' own struggles to practice the claims well after the priority date), that undue experimentation would be required to practice these claim limitations. *See* SOF¶¶ 175–80; Ex. 32 (Prud'homme) ¶¶ 148–71, 179–89, 199–207; Ex. 44 (Prud'homme Reply) ¶¶ 70–88, 100–107, 115–21; Ex. 45 (Meulien) ¶¶ 50–123, 140–48; Ex. 46 (Meulien Reply) ¶¶ 27–32. Plaintiffs' expert Dr. Murthy responded, challenging Drs. Prud'homme's and Meulien's factual allegations. Ex. 35 (Murthy) ¶¶ 630–729 (80 pages of opinions). Thus, far from conclusory, these expert opinions surrounding whether undue experimentation is required is quintessential of a fact dispute. *See Cellectis S.A. v. Precision Biosciences, Inc.*, 937 F. Supp. 2d 474, 486 (D. Del. 2013); *Intellectual Ventures I, LLC v. Canon Inc.,* 143 F. Supp. 3d 143, 156 (D. Del. 2015).

i. Moderna's Expert Testimony Is Not Conclusory

Plaintiffs claim (again) that Drs. Prud'homme and Meulien offered conclusory opinions. Op. 26–27. Specifically, Plaintiffs argue that Dr. Prud'homme's opinions regarding the overbreadth of the claims "because the '651 patent claims are not limited to specific (a) classes of the claimed lipids, (b) molar ratios, or (c) vesicle structures" and Dr. Meulien's opinions that achieving "the encapsulation percentages when formulating with one particular mRNA [] does not evidence that [one] would also be able to achieve those encapsulation percentages with larger [mRNA]" are non-specific and insufficient to show non-enablement. Op. 26. Not so. For example, regarding the breadth of the claims, Dr. Prud'homme examined the specification and found laundry lists of lipid components unbounded by proportions and type of each recited lipid. SOF¶¶ 171–73; Ex. 32 (Prud'homme) ¶¶ 110, 148–52. Dr. Prud'homme also explained that the entire '651 specification was directed to pDNA. SOF¶¶ 171–73; Ex. 32 (Prud'homme) ¶¶ 110–12. Dr.

Prud'homme also analyzed Plaintiffs' own difficulties formulating the required percentage of "fully encapsulated" mRNA years after the 2002 alleged priority date. SOF¶¶ 183–92; Ex. 32 (Prud'homme) ¶¶ 114–20. He also opined on each of the *Wands* factors, supporting his conclusions with record evidence. *Id*. SOF¶ 175. None of this is conclusory, despite Plaintiffs' omnibus citation to large swathes of Dr. Prud'homme's opinions with little-to-no explanation as to why it is "conclusory."

Likewise, Dr. Meulien's opinions are not conclusory. He identified important chemical and structural differences between nucleic acids listed in the patents. SOF¶¶ 106, 177; Ex. 45 (Meulien) ¶¶ 50–123, 143. And Dr. Heyes (Genevant's current CEO) previously agreed that a POSA "would appreciate that the method described in [the prior art] is only applicable to plasmid DNA (and not every type of nucleic acid), and ***the high encapsulation efficiency achieved for plasmid DNA using this method does not reasonably predict that mRNA will exhibit a similar encapsulation efficiency*** . . . Therefore, the results obtained for plasmid DNA using the method described in [the prior art] ***cannot be extrapolated to mRNA***." Ex. 59 (GENV-00024061) at 065. In other words, the structural and chemical differences between the nucleic acid categories, including mRNA, impacts encapsulation, which supports all of Moderna's non-enablement theories.

Because Drs. Prud'homme's and Meulien's opinions are grounded in fact and supported by an extensive record, *Alcon*, *Koito*, *Cephalon*, and *John Hopkins* are inapposite. *Alcon,* 745 F.3d at 1189 (patent challenger provided ***no evidence*** that any experimentation, let alone undue, would be necessary); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155-56 (Fed. Cir. 2004) (patent challenger had ***no evidence*** of undue experimentation); *Cephalon, Inc. v. Watson Pharms., Inc.,* 707 F.3d 1330, 1339 (Fed. Cir. 2013) (patent challenger had ***only unsubstantiated statements*** that experimentation would be "difficult," "complicated"); *Johns Hopkins University v. CellPro,*

Inc., 152 F.3d 1342, 1360–61 (Fed. Cir. 1998) (failed attempts to make claimed invention were by non-POSAs or deviated from patent). As explained above, this case is no different than *Consolidated Electric*—"[T]he fact that [mRNA] happens to belong to the [nucleic acid] kingdom did not invest [Plaintiffs] with sovereignty over this entire kingdom." *Consolidated*, 159 U.S. at 476. Yet Plaintiffs unabashedly assert that the '651 patent covers "[v]irtually ***all known LNP formulations*** for all uses of mRNA, including vaccines; irrespective of particle morphology, lipid ratios or specific lipids employed." SOF¶ 173; Ex. 55 (GENV-00272977) at 981; *see also* Ex. 32 (Prud'homme) ¶ 154. This is implausible given the only nucleic acid used in the working examples of the '651 patent is pDNA—not mRNA as required by the asserted claims.

ii. Plaintiffs' Own Undue Experimentation Is Evidence of No Enablement

Plaintiffs themselves struggled to make lipid formulations with at least 70% "fully encapsulated" mRNA as claimed in the '651 patent, including in projects in 2013–2014 and even as late as 2018—years after the alleged 2002 priority date. *See, e.g.*, SOF¶¶ 183–92. Specifically, Plaintiffs described their encapsulation of mRNA as "by no means optimal" in 2013, noting that "only 30% of the mRNA was encapsulated"—far less than the 70% encapsulation required by the '651 claims. *See* Ex. 51 (GENV-00304863 at 865); SOF¶ 187. To achieve more than 70% "fully encapsulated" mRNA as claimed, an extensive reformulation effort was carried out in which "***[h]undreds*** of formulations were generated, using a variety of different lipids and buffers, as well as adjustments to process parameters such as flow rate, concentration, incubation times, tubing identity and length." SOF¶ 188. This direct evidence of non-enablement cannot be swept aside by Plaintiffs' attempt to transform Moderna's expert opinions on disputed facts into legal questions.

Plaintiffs argue any trial and error required to practice the claims did not amount to undue experimentation and that Moderna was required to show that such trial and error was "elaborate"

and "painstaking." *See* Op. 27–28 (citing *Amgen*, 598 U.S. at 610, 614). But that is not what the law requires—just because elaborate and painstaking efforts have shown undue experimentation does not mean they are required. Regardless, even if required, Moderna's experts opined that Plaintiffs' extensive failures ***do*** show undue experimentation. SOF¶ 175. Those years of difficulties are not mere trial and error with "commonly used techniques." *Cephalon.* 707 F.3d at 1338.

Next, Plaintiffs allege that the 2013-2014 studies relate to particle size and improving encapsulation which are "unclaimed" properties. Op. 28. But Plaintiffs' struggles to "improve ***encapsulation***" is directly relevant to whether a POSA could make and use formulations with the ***claimed*** percentages of "fully encapsulated" mRNA. Plaintiffs also argue that "Moderna's experts do not contest Dr. Murthy's account of the experimental records that, after just a handful of experiments in 2013-2014, Plaintiffs achieved the claimed percentages of encapsulation of mRNA, or that the parameter adjustments that resulted in high encapsulation were taught by the patent and otherwise routine." Op. 28. This is false. Moderna ***contested*** Dr. Murthy's opinion that making "hundreds" of formulations was "routine" and that Dr. Palmer was "quickly successful"—a clear fact dispute. *E.g.*, Ex. 45 (Meulien) ¶¶ 146–47; Ex. 60 (Prud'homme Tr.) 267:14–18, 267:19–268:3, 275:6–8; SOF¶¶ 104–09, 184–92. Plaintiffs also complain that Moderna "cite[d] experimental records of the underlying 2013 and 2014 experiments such as lab notebooks." Op. 28. But the report's author confirmed that they needed to make "hundreds" of formulations to achieve the claimed mRNA encapsulation—just as the report described. SOF¶ 189. Regardless, if Plaintiffs now contend there are differences between the summary report and the underlying data, these too are fact disputes for the jury. And while Plaintiffs argue that there is no evidence that the failed 2013-2014 studies attempted to follow the methods of the '651 patent, Op. 27, Plaintiffs'

own expert Dr. Murthy claimed these experiments were "***within the teachings of the '651 patent***." Ex. 36 (Murthy) ¶ 622.

Finally, Plaintiffs fault Moderna for "not identify[ing] the requisite particular embodiments, such as a specific combination of lipids, that could not be used to achieve the claimed percentages." Op. 28. But this argument borders on the absurd—Moderna's whole argument is that the asserted claims do ***not*** teach a POSA how to make or use lipid formulations with >70% "fully encapsulated" mRNA as claimed. Ex. 50 ('651 patent), claim 1, 13, 14.

iii. Experimentation by Plaintiffs, Moderna, and Others Also Does Not Support Enablement

Plaintiffs argue that they, Moderna, and others had no difficulty practicing the claims. Op. 29–31. But again, Plaintiffs ignore that Moderna and its experts dispute this.

Regarding Plaintiffs' work, Plaintiffs argue that in 2009 "Plaintiffs' inexperienced scientist practiced the claims . . . in a single day, by making adjustments taught by the patent." Op. 29. But the alleged priority date for the '651 patent is in 2002—not 2009 (seven years later)—and Plaintiffs have no evidence that this post-priority date work was enabled as of 2002. To the contrary, Prud'homme explained that Mr. Reid's experiments were based upon the company's "research foundations" of "***many, many, many experiments***." Ex. 60 (Prud'homme Tr.) 267:7–268:3; SOF¶¶ 80, 83, 185. In fact, years later in 2014 (12 years after the alleged priority date), Plaintiffs attempted to replicate Mr. Reid's experiments; it took ***two months*** and ***hundreds*** of formulations to do so. SOF¶ 190; Ex. 60 (Prud'homme Tr.) 275:6–8. Plaintiffs' own documents show that they continued to struggle in achieving the claimed encapsulation rates for mRNA into 2018. SOF¶ 192; *see also Cephalon*, 707 F.3d at 1339 ("[E]xperimentation was unreasonable, for example, where it was found that eighteen months to two years' work was required to practice" claims); *Vita Zahnfabrik H. Rauter GmbH & Co. KG v. Dentsply Int'l, Inc.*, 2006 WL 8437644, at *8 (C.D. Cal.

June 21, 2006), *aff'd*, 278 F. App'x 1013 (Fed. Cir. 2008) (finding 2–4 years of development raised question of fact as to whether the specification was enabling). Finally, Dr. Prud'homme analyzed the 2009 and 2013–2014 experiments and confirmed that Plaintiffs achieved 70+% encapsulation of mRNA by optimizing a ***trade secret*** buffer EDTA that was ***not*** disclosed in the '651 Patent. SOF¶¶ 196–205. In a prior litigation, Plaintiff Arbutus asserted that it kept the use of EDTA as a trade secret and sued another company for misappropriating it. SOF¶¶ 196–201. In fact, Arbutus's Chief Technical Officer testified that EDTA was "extremely important" for encapsulation. SOF¶¶ 200. The use of that trade secret ***cannot*** be evidence that the '651 Patent was enabling. *Union Pacific Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690–91 (Fed. Cir. 2001); *Convolve, Inc. v. Compaq Comput. Corp.*, 2013 WL 3285331, at *18-*19 (Fed. Cir. July 1, 2013). Moderna thus did ***not*** "ignore" evidence of Plaintiffs' formulation failures (Op. 29), Plaintiffs just disagree with Moderna's interpretation of it—i.e., a fact dispute.

Plaintiffs also suggest Moderna easily practiced the asserted claims without undue experimentation by pointing to Dr. Woods' work in 2012—10 years after the alleged priority date. But as Plaintiffs admit, it is ***disputed*** whether her work applied the methods in the '651 patent. *See* Op. 29–30 (citing conflicting opinions); Ex. 32 (Prud'homme) ¶¶ 79, 82, 117–18; SOF¶¶ 92–99.

As for other researchers, ***it is contested*** "that many researchers used the methods in the patents and had no apparent difficulty achieving the claimed invention without undue experimentation." Op. 31. Much of this evidence is based on Jeffs 2005 (*see* Ex. 35 (Murthy) ¶¶ 709, 712, 727, 1416), but Dr. Prud'homme disagreed that "Jeffs 2005 is equivalent to the disclosures of the '651 patent." Ex. 44 (Prud'homme Reply) ¶¶ 141, 265–66; SOF¶ 193. Likewise, almost all of Dr. Murthy's purported evidence is based on post-filing examples of mRNA encapsulation—in some case more than 15 years after the alleged priority date. *See* Ex. 35

(Murthy) ¶¶ 701, 709, 712, 727, 1416. And Dr. Prud'homme "disagree[d] that work post-dating 2002 is probative of the level of predictability in the art as of 2002. There is no indication that the researchers used only pre-2002 knowledge or followed the methods of the '651 patent only (or even methods existing as of 2002 more generally)." Ex. 44 (Prud'homme Reply) ¶ 79.

b. Plaintiffs' Attacks on Moderna's Fact-Based Arguments Fail

Plaintiffs next raise a hodge podge of disagreements with Moderna's enablement arguments, but none have merit. First, Plaintiffs again argue that Moderna relies on unrecited properties. Op. 30–31. But as explained above, Moderna opined on these properties (e.g., transfection efficiency, toxicity, LNP stability, and other effects) because Plaintiffs relied on them as distinguishing their purported invention from the prior art. *See* § IV.B.1.b, *supra*. Moreover, these purported advantages are relevant to the alleged utility (or lack thereof) of the patents—i.e., the "use" in how to make and ***use*** the claimed invention under the enablement doctrine. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999).

Second, Plaintiffs argue that Moderna's expert opinions "traduce[] the black-letter rule that 'the enablement requirement is met if the description enables any mode of making and using the invention.'" Op. 32 (quoting *Johns Hopkins*, 152 F.3d at 1361). Moderna does not dispute this legal standard. But Moderna ***does*** dispute that the '651 patent describes "***any*** mode"—***even one***—to make the claimed formulations with >70% "fully encapsulated" mRNA because it is solely focused on pDNA. *See* Ex. 50 ('651 patent) at 14:11–19:2; Ex. 32 (Prud'homme) ¶¶ 181–89. As Plaintiffs admitted, any disclosed method for pDNA in the specification would require different parameters for mRNA. *See* Ex. 32 (Prud'homme) ¶ 114–20, 164–65, 167–71, 181–89, 199–207. For example, Dr. Heyes stated in 2014 that "mRNA does not encapsulate as easily as smaller payloads; using standard processes, encapsulation efficiencies were often only 30–40%." Ex. 51, GENV-00304863 at 864–65. And, as explained above, Arbutus had to test "hundreds" of

formulations varying many parameters, including the use of a trade secret not disclosed in the '651 patent, to learn how to adequately encapsulate mRNA years after the alleged priority date. SOF¶ 189. At a minimum, this evidence raises a fact dispute as to whether a POSA could practice the recited claim limitations including "at least [about] 70% [/80%/90%] of the mRNA . . . is fully encapsulated" without undue experimentation in 2002.

Plaintiffs' final argument is that it is irrelevant that a POSA would not know how to measure "partial encapsulation." Not so. The asserted claims of the '651 patent require "fully encapsulated" mRNA, which is construed to mean "fully, ***as distinct from partially*** contained inside the lipid vesicles." Ex. 50 ('651 patent) at claims 1, 13, 14; D.I. 266 at 32–37. This construction thus identifies two states of encapsulation—"full" and "partial." But there is ***no*** defined meaning of "fully" or "partially" encapsulated mRNA. SOF¶¶ 194–95. And there was no consistent way to measure "encapsulation" at the alleged priority date. SOF¶¶ 194–95. Even Dr. Murthy conceded that a POSA would need to measure the amount of "fully encapsulated" mRNA to practice the '651 claims. Ex. 35 (Murthy) ¶ 681 ("the adjustments made . . . to achieve these full encapsulation percentages constituted predictable, routine, and ***easy-to-test*** variations"), ¶ 685 ("formulating and ***testing the encapsulation of particles*** would have been relatively ***quick*** and ***easy*** in light of the teachings of the '651 patent."). In sum, the '651 patent could not have taught a POSA how to achieve the claimed formulations if there was no way to know if the claim limitations were met. *Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 614 (D. Del. 2022), *aff'd*, 81 F.4th 1362 (Fed. Cir. 2023) (finding no enablement where "[t]here is no guidance or direction as to how to identify antibodies that satisfy the claims' limitations other than by utilizing trial and error.").

C. Disputed Issues of Material Fact Preclude Summary Judgment on Derivation

The named inventors of the '651 patent, specifically, Ian MacLachlan, derived the asserted claims of the '651 patent from Moderna. Prior to the filing the '651 patent, none of the patents or

applications in the '651 Family tracing back to 2002 claimed lipid formulations comprising mRNA. SOF¶¶ 207–08. It was only after Dr. MacLachlan received a copy of a Moderna patent application in 2012, describing lipid formulations comprising mRNA, that the '651 patent was filed. SOF¶¶ 207–08, 216–19. On these facts and those below, a reasonable jury could certainly find that Moderna conceived of the claimed invention prior to Plaintiffs and that Moderna's conception was communicated to Plaintiffs, as is required to show derivation under § 102(f). *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003). Plaintiffs' motion for summary judgment ignores the bases for Moderna's derivation defense, attempts to cover up the lack of any supporting disclosure for the claims of the '651 patent in the 2002 priority application, and misrepresents Dr. Prud'homme's (Moderna's expert) testimony. The motion should be denied.

1. Whether Moderna was First to Conceive of the Claimed Invention Is Disputed, Precluding Summary Judgment

The first prong of the derivation test asks whether someone other than the named inventors first conceived of the invention claimed in the '651 patent. *See Eaton*, 323 F.3d at 1344. The '651 patent claims priority back to an application filed in 2002. But Plaintiffs' earliest possible conception date is June 13, 2014, when Plaintiffs filed the application that issued as the '651 patent with claims to lipid formulations comprising "fully encapsulated" "mRNA." SOF¶¶ 207–211. Although Plaintiffs contend that they are entitled to an earlier conception date of 2002 based on the '651 patent's priority chain, they have submitted no evidence supporting that assertion. Instead, the evidence shows that Plaintiffs did not conceive of the claimed inventions any earlier than June 13, 2014. Prior to this date, none of the patents or applications in the '651 Family described, enabled, or even claimed lipid formulations comprising mRNA. SOF¶¶ 207–08. The 2002 priority application was directed to formulations for pDNA, which was Plaintiff Arbutus's research focus at the time. SOF¶¶ 171–72, 210. As a result, Dr. Prud'homme opined that Plaintiffs may not rely

on the earlier patents and applications in the '651 Family to assert conception prior to June 13, 2014. SOF¶¶ 209–11; *see also PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) ("It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.").

By contrast, it is undisputed that, under Plaintiffs' view of the claims for infringement purposes, Moderna conceived of and constructively reduced to practice the claimed invention much earlier than June 13, 2014, as exemplified by Moderna's patent application WO648, filed December 14, 2012, and published June 20, 2013. Ex. 18 (WO648) at Cover; SOF¶¶ 212–15. Indeed, Plaintiffs and their expert, Dr. Murthy, do not dispute that Moderna's WO648 discloses ***all*** limitations of the asserted claims of the '651 patent. SOF¶¶ 215; Ex. 35 (Murthy) ¶¶ 492–93. These facts establish conception by Moderna prior to Plaintiffs' alleged conception date.

In an attempt to sidestep these facts, Plaintiffs dismiss Moderna's conception argument as a "smuggle[d] section 112 defense." Op. 34. But Plaintiffs ignore that a priority date challenge is distinct from a § 112 defense, including because Plaintiffs—not Moderna—bear the burden to show entitlement to their asserted priority date. Because WO648 is anticipatory prior art as of the '651 patent filing date, Plaintiffs must come forward with evidence "that [WO648] is not prior art because the asserted claim[s are] entitled to the benefit of a filing date prior to the alleged prior art. This requires [Plaintiffs] to show not only the existence of the earlier application, but why the written description in the earlier application supports the claim." *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *see also Nat. Alts. Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018) ("[C]laims . . . are not entitled to priority under § 120 at least until the patent owner *proves* entitlement . . ."") (emphasis in original); 35 U.S.C. § 120 (earlier

application must support and enable later-filed claims under § 112). Plaintiffs' only attempt to meet their burden is ***a single conclusory footnote***. Op. 35 n.5. Plaintiffs have otherwise done nothing in their brief to establish that their 2002 priority application meets the § 112 written description requirement. Indeed, ***no*** party moved for summary judgment on written description of the '651 patent given that issue is hotly contested. Nor can Plaintiffs establish that the 2002 priority application meets the enablement requirement of § 112 by pointing to a single 2009 experiment. Plaintiffs' motion should be denied for that reason alone. *See* Ex. 32 (Prud'homme) ¶¶ 335–42.

2. Plaintiffs Do Not Dispute That Moderna's Conception Was Communicated to Named Inventor Ian MacLachlan

As to the second prong of derivation, communication of the prior conception to the patentee, Plaintiffs do not dispute that in 2014, named inventor Ian MacLachlan asked his colleague for analysis of Moderna's patents while preparing to present at a conference on mRNA. SOF¶¶ 216–19; Ex. 62 (Jan. to Feb. 2014 Email Chain). As requested, his colleague responded with a summary of Moderna's WO648, attached a copy of WO648 to the email, and praised Moderna for successfully encapsulating mRNA without the use of the trade secret EDTA that Plaintiffs had come to depend on. SOF¶¶ 216–19. Several months after Dr. MacLachlan analyzed Moderna's WO648, Plaintiffs filed the application that led to the '651 patent, which for the first time included claims to "mRNA" formulations. Ex. 63 ('651 Patent FH). These undisputed facts establish communication to the patentee prior to Plaintiffs' application for the '651 patent.

3. Rather Than Engage with Unfavorable Facts, Plaintiffs Rely on Irrelevant Evidence and Attorney Argument

Plaintiffs' motion does not address Moderna's clear evidence of conception and communication described in §§ IV.C.1 and IV.C.2. Instead, Plaintiffs focus on an irrelevant 2009 experiment and mischaracterize Dr. Prud'homme's testimony. Both arguments lack merit.

First, Plaintiffs sidestep the specification's lack of disclosure by claiming that "***Plaintiffs'***

Mr. Reid" supposedly achieved the claimed levels of "fully encapsulated" mRNA. Op. 34. But Plaintiffs intentionally omit that Mr. Reid is ***not*** a named inventor. SOF¶¶ 206–07. That means whatever work non-inventor Mr. Reid did has no bearing on when and whether the named ***inventors*** conceived of the claimed invention. *Invitrogen Corp. v. Clontech Lab'ys Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005) ("conception" is "in the mind of the ***inventor***"). If Plaintiffs are instead arguing that Mr. Reid's work demonstrates that the '651 claims are enabled by the 2002 application, Plaintiffs cite nothing in support. *Id.* at 1068 ("Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony. It does not, and cannot, support [movant's] burden on summary judgment."). For Mr. Reid's work to matter at all, Plaintiffs would need to show that he followed the teachings of the 2002 application in his 2009 work. Plaintiffs cite nothing—no testimony from Mr. Reid, no documents, and no expert testimony—showing that is what Mr. Reid did. Instead, Plaintiffs make the conclusory assertion that Dr. Prud'homme's opinions regarding the irrelevance of Mr. Reid's work are "legally insufficient." Op. 34. But it is Plaintiffs'—not Moderna's—arguments regarding Mr. Reid that are insufficient to carry ***their*** summary judgment burden. As Dr. Prud'homme pointed out, Plaintiffs' expert, Dr. Murthy, never analyzed whether Mr. Reid's 2009 experiment followed the parameters disclosed in the 2002 application as opposed to other techniques, including techniques developed post-2002. Ex. 44 (Prud'homme Reply) ¶ 140. The lack of any supporting evidence is unsurprising because Mr. Reid used an EDTA buffer in his 2009 experiments—a trade secret ***not*** disclosed in the 2002 application—to increase mRNA encapsulation from 55–60% to 95%. Ex. 13 (Reid Notebook) at 588–91; SOF¶¶ 198–203; *see* § IV.B.2.a.iii (discussing EDTA trade secret). Thus, Mr. Reid's 2009 work is "not probative of whether the claims" of the '651 patent are "described and enabled by the priority applications as

of 2002." Ex. 44 (Prud'homme Reply) ¶ 140.

Second, Plaintiffs assert Dr. Prud'homme opined that WO648 "discloses each limitation [of the asserted claims] only insofar as the '651 patent's priority application adequately describes and enables the claimed invention," and thus, Moderna cannot establish derivation. Op. 35 (emphasis omitted). That is ***false***. Tellingly, Plaintiffs do not quote a single statement from his deposition. *Id.* Instead, Dr. Prud'homme opined that that the "fully encapsulated" limitation of the asserted claims is indefinite and is not disclosed ***anywhere*** in the art. SOF¶ 214. For derivation, however, Dr. Prud'homme applied "Plaintiffs' interpretation of the claims for infringement purposes," including Plaintiffs' argument that "fully encapsulated" mRNA is shown by a measuring "encapsulation." Ex. 32 (Prud'homme) ¶ 343; Ex. 60 (Prud'homme Tr.) at 324:9–17. It is entirely permissible for an expert to propound this type of opinion. *See NetFuel, Inc. v. Cisco Sys. Inc.*, 2020 WL 1274985, at *4–6 (N.D. Cal. Mar. 17, 2020) (expert may assume "[Plaintiff's] understanding of the construed claims is correct, and then . . . demonstrate how, in his opinion, each element of the claim[] is found in the prior art"); *HSM Portfolio LLC v. Elpida Memory Inc.*, 160 F. Supp. 3d 708, 726 (D. Del. 2016) (crediting expert who "performed a[n] . . . anticipation analysis that merely relies on the claim interpretations that follow from Plaintiffs' infringement theory"). Critically, and what Plaintiffs ignore, is that even under their interpretation of the claims, Plaintiffs' 2002 priority application still does not disclose "fully encapsulated" ***mRNA*** as claimed in the '651 patent. Ex. 44 (Prud'homme Reply) ¶ 142; Ex. 60 (Prud'homme Tr.) at 323:21–324:17. Plaintiffs' assertion that Dr. Prud'homme is trying to "have it both ways," Op. 35, is nothing more than a poorly constructed strawman and does not support granting summary judgment.

V. CONCLUSION

For the reasons above, this Court should deny Plaintiffs' motions for summary judgment.

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August 22, 2025

CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2025, caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 22, 2025, upon the following in the manner indicated:

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